DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

1680d

August 30, 2001

WARNING LETTER NYK 2001-119

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gale Ketcham, Administrator
Mid Hudson Medical Group
30 Columbia Street
Poughkeepsie, New York 12601

RE: Facility ID Number 217679

Dear Mr. Ketcham:

Your facility was inspected on August 22, 2001 by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Repeat Level 2 finding at your facility:

- ***The measured fog density in the darkroom is equal to 0.1.***

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and it indicates a failure by your facility to implement permanent correction of a problem found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate, obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter each step your facility is taking to correct this violation and to prevent the recurrence of similar violations.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- ***Failure to establish and comply with adequate procedures for infection control.***
- ***Failure to document corrective action before further exams for a failing image score, or a phantom background optical density or density difference outside the allowable regulatory limits.***
- ***Two (2) of six (6) mammography reports reviewed at random failed to contain an acceptable assessment category.***

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, at U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York, 14202. If you have any questions, you may reach me by telephone at (716) 551-4461 extension 3117.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

Sincerely,

Robert L. Hart
Acting District Director

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
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